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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,420	04/16/2004	Kyungyoon Min	F-6097 (0360-0146)	9851

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,420	MIN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/07, 4/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on 12 February 2007. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claim 15 is rejected under 35 U.S.C. 102(a) as being anticipated by US 6,632,191 to Headley.

With regard to claim 15, Headley discloses a blood processing chamber 21 wirh a plurality of containers 24, 28, with associated flow tubing and a source flow path 10 that may process blood while in fluid communication with a blood source (see FIG 2, column 4, lines 1-12). With regard to applicant's claim limitation drawn to the circuit adapted to process blood while the circuit is connected to the source but fluid flow from the source has stopper, such a limitation is considered by the examiner to be a recitation of the functional operation of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed dies not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations (see MPEP 2114). It is the position of the

examiner that since source flow path 10 comprises a valve 22, the circuit disclosed by Headley is capable of functioning as claimed by applicant, meeting the limitations of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6, 8-12, 14, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al.

In the specification and figures, Headley discloses the method susbstantially as claimed by applicant. With regard to claims 1-3 and 21, Headley discloses a method for collecting and separating whole blood comprising the steps of providing a disposable blood separation set (see FIG 1) that mounts on a reusable separator and control unit 20 (see column 3, lines 15-25). The disposable set comprises a cannula 10 or fluid flow path for communicating with a source, and a processing chamber 21.

Headley discloses that prior art systems steps of connecting cannula 10 to a donor, flowing fluid from the donor to an initial container 12 with anticoagulant, disconnecting the patient from the set before any (which includes all) blood is processed, mounting the set in a centrifuge, processing the blood through in processing chamber 13, processing the collected blood to separate into the desired components,

and disconnecting the donor from the system before the separation process is complete (see column 1, lines 25-60).

Headley discloses that the disposable set is mounted in the reusable assembly prior to connecting the set to a patient and that the patient is disconnected before processing begins. However, the language of the claim does not set forth a specific order of the steps performed in the method. It is improper to read a specific order of steps into method claims where the language of the method claims did not impose a specific order on the steps and the specification did not require a particular order (see MPEP 2111.01(II)). Applicant's specification, at paragraphs 0021 and 0025, indicates that the disposable set may be mounted on the reusable device before or after the set is connected to the donor and that the donor may be separated from the processing set before processing begins. As such, since Headley discloses all the steps in the claimed method and applicant does not specify an order of the claimed steps, it would have been obvious to rearrange the steps disclosed by Headley to arrive at the claimed method.

With regard to claims 4-6, 14, Headley discloses that the rotor or collection chamber in the disclosed embodiment has a variable volume (see column 3, lines 15-34). It has been held that where the general conditions of a claim are disclosed in the prior art, it is within the skill of a worker in the art to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). Since Headley specifically discloses that the volume of blood collected may vary from patient to patient,

it is the position of the examiner that the amount of whole blood collected is a result-effective variable, the optimization of which is within the skill of a worker in the art.

With regard to claims 8 and 9, Headley discloses that in some systems, the blood separation system is remote from the donor (see column 1, lines 37-39).

With regard to claim 10, Headley discloses that the blood source is a "donor," (see column 1, lines 25-30), which is well-known in the art to comprise a human donor (see US 5,906,589 to Gordon et al that discloses apheresis blood supply as typically a human donor/patient at column 3, lines 55-60).

With regard to claims 11 and 12, Headley discloses that the system and method may be use to separate all the collected blood into constituent components simultaneously (see column 4, lines 20-30) or sequentially, wherein plasma is removed from the blood before RBC separation (see column 4, lines 13-16).

With regard to claims 18 and 19, Headley discloses the device substantially as claimed by applicant (see rejection above) with the exception of an initial collection chamber with anticoagulant. Headley discloses that in a prior art configuration, blood collection systems comprised an initial collection container 12 with an anticoagulant that received blood for processing in a location remote from the donor (see column 1, lines 25-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an initial collection container with anticoagulant to the collection circuit disclosed by Headley, since Headley discloses that such initial collection containers were well-known in the art to perform blood separation at a location remote from the donor.

With regard to claims 16 and 17, Headley discloses a typical disposable bag set that is capable of receiving a unit, or 450 mL of whole blood (see US 5,651,766 to Kingsley et al, column 1, lines 10-17, incorporated by reference into the Headley disclosure).

With regard to claim 20, Headley discloses a method of separating whole blood into components comprising the steps of providing a disposable set for use with a reusable controller, wherein the circuit includes a fluid flow path 10 for communication with a source, a blood processing chamber 21; connecting the fluid path 10 to a source, collecting blood, processing collected blood, and disconnecting the source from the circuit.

Headley discloses that the disposable set is mounted in the reusable assembly prior to connecting the set to a patient. However, the language of the claim does not set forth a specific order of the steps performed in the method. It is improper to read a specific order of steps into method claims where the language of the method claims did not impose a specific order on the steps and the specification did not require a particular order (see MPEP 2111.01(II)). Applicant's specification, at paragraphs 0021, indicates that the disposable set may be mounted on the reusable device before or after the set is connected to the donor. As such, since Headley discloses all the steps in the claimed method and applicant does not specify an order of the claimed steps, it would have been obvious to rearrange the steps disclosed by Headley to arrive at the claimed method.

6. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 6,743,192 to Sakota et al.

In the specification and figures, Headley discloses the method substantially as claimed by applicant with the exception of providing additional whole blood bags and pooling whole blood before processing. Sakota discloses a blood apheresis apparatus and method comprising a disposable fluid circuit with a phlebotomy needle 24 that connects to a donor. The phlebotomy needle may be replaced with a whole blood bag in case whole blood is to be pooled and then supplied to the apheresis system (see column 6, lines 55-65) in order to increase the amount of whole blood processed in a single round of apheresis (see column 2, line 56 to column 3, line 37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the additional containers and pooling whole blood as disclosed by Sakota in the process disclosed by Headley in order to increase the volume of whole blood processed, as taught by Sakota.

Response to Arguments

7. Applicant's amendment and arguments, filed 12 February 2007, have been entered and considered. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER